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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,088	07/26/2001	Alessandro Lambiase	36226/125733	6075

7590 09/06/2006

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EXAMINER

HAGOPIAN, CASEY SHEA

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/890,088	<b>Applicant(s)</b> LAMBIASE, ALESSANDRO	
	<b>Examiner</b> Casey Hagopian	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 13-15, 17-21 and 23-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15, 17-21 and 23-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Receipt is acknowledged of Applicant's Amendment/Remarks filed 3/13/2006 and Request for Continued Examination filed on 6/13/2006. It should be noted that this case has been transferred from examiner David Vanik to examiner Casey Hagopian.

### **MAINTAINED REJECTIONS**

The following rejections are maintained:

#### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13-15, 17-21 and 23-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Lambiase (WO 98/48002). Lambiase discloses methods of treating pathologies affecting the internal tissues of the eye by administering between 10 to 500 µg/ml of nerve growth factor to an individual (abstract and page 12, lines 14). The NGF can be administered either topically or over the ocular surface of an individual and treats corneal and/or conjunctival affects (page 12, line 31 – page 13, line 23). In another embodiment, the NGF may be administered by introduction into the anterior chamber of the eye (page 12, lines 17-20). Like the instant application, the NGF may be in the form of an ophthalmic solution or gel and may be administered via a bandage or medical

Art Unit: 1615

contact lens (page 12, lines 10-13). The NGF medicament can be of human origin and can be used to treat disorders originating from laser treatment (Claim 9, 15).

It is the examiner's position that, inherently, the composition advanced by Lambiase, when injected into the eye, treats the same eye-related disorders as the instant application. Since the essential elements of the Lambiase composition and method are identical to the instant compositions and methods (that is, injecting a composition comprising 10 to 500  $\mu\text{g/ml}$  of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Lambiase anticipates the compositions enumerated in the instant claim set.

4. Claims 13-15, 18-19, 21, 24-28 and 30-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Finkenaur et al. (EP 0312208 A1). Finkenaur discloses aqueous gel formulations comprising 1 to 500  $\mu\text{g/ml}$  of a polypeptide growth factor, such as nerve growth factor (abstract and page 3, lines 25-48). Said nerve growth factor can be used for wound healing in the anterior chamber of the eye (abstract). Said wound healing composition can be delivered to an individual via a bandage (page 2, lines 49-50).

It is the examiner's position that, inherently, the composition advanced by Finkenaur, when injected into the eye, treats the same eye-related disorders as the instant application. Since the essential elements of the Finkenaur composition and method are identical to the instant compositions and methods (that is, injecting a

Art Unit: 1615

composition comprising 1 to 500 µg/ml of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by Finkenaar anticipates the compositions enumerated in the instant claim set.

### ***Response to Amendment***

5. As a result of Applicant's amendment filed 3/13/2006, the 35 USC 112 rejections are hereby withdrawn. Also, the cancellation of claims 16 and 22 renders the art-based rejections of those claims moot.

### ***Response to Arguments***

6. Applicant's arguments filed 3/13/2006 have been fully considered but they are not persuasive. It is the position of the examiner that the Advisory Action mailed 5/15/2006 adequately addressed applicant's Remarks dated 3/13/2006. It should be noted that Applicant did not submit any additional remarks at the time of the Request for Continuing Examination.

7. In response to applicant's arguments in regards to the art-based rejections (pages 11-23), it is the examiner's position that, inherently, the methods of treating eyes with NGF advanced by both Lambiase and Finkenaar would treat the same internal tissues of the eye as set forth in the instant claim set. Since the essential elements of the Lambiase and Finkenaar compositions and methods are identical to the instant

Art Unit: 1615

compositions and methods (that is, injecting or contacting the surface of the eye with a composition comprising 10 to 500 mg/ml of nerve growth factor to an individual), the composition would inherently treat the same disorders as the compositions set forth in the instant application. Moreover, the carriers set forth in both Lambiase and Finkenaure and modes of delivery (solutions, gels, suspensions, ointments, and gels) are the same as those described in the instant claim set. Since the essential elements of the methods appear to be the same, the internal tissues to be treated would also necessarily be the same. As such, it is the examiner's position that the composition advanced by Lambiase anticipates the compositions enumerated in the instant claim set. It is also respectfully submitted that, contrary to Applicant's assertions, all of the claim limitations were properly examined in the 9/8/2005 Final Rejection. Specifically, the amount of growth factor being used (10-500 ug/ml) and the delivery means (medicinal contact lens contacting the NGF with the eye) are cited on page 12, lines 7-14). In closing, it should be noted that the examiner has carefully considered Applicant's arguments and respectfully concludes that for the reasons set forth above, the art-based rejections are maintained.

#### ***Pertinent Art***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Urso (USPN 6,063,757) is cited as patents of interest in its disclosure of NGF for use in ophthalmic wound healing. Unlike the instant application, Urso uses a maximum of 1000 mg/ml (1µg/ml) in the formulation.

***Conclusion***


9. All claims have been rejected; no claims are allowed.

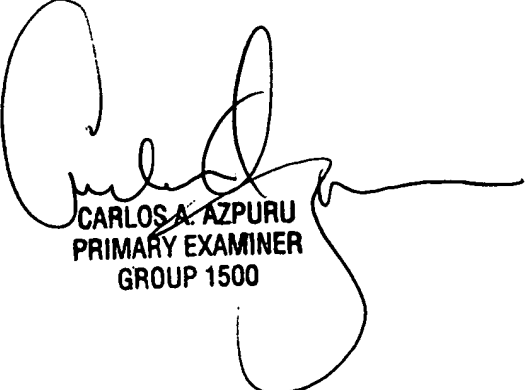
***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Tuesday through Friday from 8:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Casey Hagopian  
Examiner  
Art Unit 1615

  
CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500